UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,110	03/30/2001	Hwa-Chain Robert Wang	4350.000800	9178

23720 7590 01/30/2004

WILLIAMS, MORGAN & AMERSON, P.C.
10333 RICHMOND, SUITE 1100
HOUSTON, TX 77042

EXAMINER	
BELYAVSKYI, MICHAIL A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/822,110	WANG, HWA-CHAIN ROBERT	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9, 12, 32-37, 42-52 and 61-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *9,12,61-63 and 66* is/are allowed.

6)☒ Claim(s) *1-8, 32- 37, 42-52 , 64, 65 and 67-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/03/03 has been entered.

Claims 1-9, 12, 32-37, 42-52 and 61-75 are pending and under consideration in the instant application.

2. In view of the amendment, filed 11/03/03 only the following rejections remain.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8, 32-37, 42-52 , 64- 65 and 67-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record set forth in the Office Action, filed on 09/30/02.

Applicant's arguments, filed 11/03/03 have been fully considered, but have not been found convincing.

Applicant asserts that: (i) the terms "about" and "at least" serves reasonably to define the claimed invention ; (ii) previous Examiner-in Charge of the case has recommended the use of the term "approximately" as a substitute for the word "about".

Contrary to Applicant's assertions, the use of term "about" and "approximately" in the instant application refers to the number of amino acid of SEQ ID NOs: 3-76 which does render the claims indefinite. It is unclear how many amino acids constitute "about" or 'approximately". One of skill in the art would not know if applicant meant 14 amino acid or as many as 70 amino acids, or even more and this is critical for the claimed inventions.

It is also noted that there is no record in the file that the previous Examiner-in Charge suggested that the term "approximately" being definite and free from the rejection.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 33-37 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection for the reasons of record set forth in the Office Action, filed on 09/30/02.

Applicant's arguments, filed 11/03/03 have been fully considered, but have not been found convincing.

Applicant asserts that original claim 32 clearly defines a genus of peptide and polypeptide that may further comprise at least one detectable label.

Contrary to Applicant's assertion the Specification and the original claim 32 do not provide a clear support for the claimed species of generic "detectable label" for an isolated peptide or polypeptide wherein said at least a first label is a labelled secondary antibody that specifically binds to said peptide or said polypeptide (claim 33); wherein said radiolabel comprises 3H, 14C, 32P, 35S, 90Y, 99Tc, 125I, or 131I (claim 34), wherein said chromogenic label comprises alkaline phosphatase, peroxidase, beta-glucuronidase, beta-D-glucosidase, beta-D-galactosidase, urease, glucose oxidase/peroxidase, or galactose oxidase/peroxidase (claim 35); wherein said fluorescent label comprises a fluorescent protein, fluorescein, rhodamine, or auramine (claim 36); or wherein said fluorescent protein comprises at least a first green fluorescent protein, or at least a first humanized green fluorescent protein (claim 37).

See, In re Ruschig, 154 USPQ 118, where a species of a properly described genus was found not to be described. A generic or a sub-generic disclosure cannot support a species unless the species is specifically described

The specification and the claims as originally field only support antibody or antigen-binding fragment that comprising a first detectable label, wherein radiolabel comprises 3H, 14C, 32P, 35S, 90Y, 99Tc, 125I, or 131I (claim 34), wherein said chromogenic label comprises alkaline phosphatase, peroxidase, beta-glucuronidase, beta-D-glucosidase, beta-D-galactosidase, urease, glucose oxidase/peroxidase, or galactose oxidase/peroxidase (claim 35); wherein said fluorescent label comprises a fluorescent protein, fluorescein, rhodamine, or auramine (claim 36); or wherein said fluorescent protein comprises at least a first green fluorescent protein, or at least a first humanized green fluorescent protein (claim 37).

7. Claims 1-8, 32- 37, 42-52 , 64, 65 and 67-75 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising SEQ ID NO: 2, a peptide consisting of residues 1-322 of SEQ ID NO: 2, and peptides consisting of SEQ ID NOS: 3-76, said SEQ ID NO: 2/peptides in a pharmaceutically acceptable excipient to be used to generate antibodies which recognize non-human p33 to diagnose the therapeutic effectiveness of cancer treatments; and wherein the immune complexes (said peptides/polypeptide--antibody) can be detected indirectly with another labeled antibody; a kit comprising said peptides, does not reasonably provide enablement for any isolated peptide/polypeptide from 14 to about 20/30/40/50/60/70 amino acids in length comprising or consisting essentially any one of SEQ ID NOS: 3-76, any other labeled peptide/polypeptide thereof for detection, diagnostic, or therapeutic purposes, any nucleic acid encoding said peptides/polypeptide, or any antibody to said peptide/polypeptide in a pharmaceutically acceptable excipient to be used for in vivo therapy of any disease, or for diagnosis of the therapeutic effectiveness of any disease other than cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the reasons of record set forth in the Office Action, filed on 09/30/02.

Applicant's arguments, filed 11/03/03 have been fully considered, but have not been found convincing. Also, it is noted that applicant does not addressed the issue of how to use any peptide of p33 or any antibody which binds to p33 as a therapeutic treatment regimen for patients suffering from cancer set forth in the Office Action, filed on 09/30/02.

Applicant asserts that: (i) Specification clearly satisfies the "make and use" requirement of the statute, by providing several examples of peptides and polypeptides that comprise one or more amino acid sequence disclosed in the Specification, (ii) the pending claims are not directed to antibody composition.

Contrary to Applicants assertion, the claims as written encompass the genus of peptide and polypeptide amino acid sequences. The genus encompasses peptides wherein such peptides have numerous differences in amino acid sequences.

Applicant discloses a single polypeptide comprising SEQ ID NO: 2 (491 residues), a peptide consisting of amino acid residues 1-322 of SEQ ID NO: 2, and peptides consisting of SEQ ID NOS: 3-76 in the instant specification. Applicant has taught a polypeptide comprising SEQ ID NO: 2, peptides consisting of SEQ ID NOS: 3-76 and a peptide consisting of amino acid residues 1-322 of SEQ ID NO: 2. Applicant has not taught how to make and/or use any isolated peptide from 14 to about 20/30/40/50/60/70 amino acids in length other than peptides consisting of SEQ ID NOS: 3-76. The structural and functional characteristics of said peptides are not defined in the claim. Further, applicant has not taught how to make or use any peptide as claimed labeled with

a spin label, a radiolabel, a fluorogenic label, a chromogenic label, an chemiluminescent label, a fluorescent label, or any other type of label.
"Comprising" and "consisting essentially" are considered open-ended claim language and includes amino acid residues outside of the specified peptide. Therefore, a peptide "comprising" or "consisting essentially" from 14 to about 20/30/40/50/60/70 amino acids in length of SEQ ID NOS: 3-76 includes an unlimited number of amino acid sequences "comprising" or "consisting essentially" an unlimited number of polypeptides. The disclosure of SEQ ID NOS: 3-76 cannot support the entire genus of peptides from 14 to about 20/30/40/50/60/70 as part of their sequence.

It is known in the art that even single amino acid changes or differences in a proteins amino acid sequence can have dramatic effects on the protein's function. For example, Mikayama et al. (PNAS, 1993. 90: 10056-10060) teach that the human glycosylation factor (GIF) protein differs from human macrophage migration inhibitory factor (MIF) by a single amino acid residue (see Figure 1 in particular). Yet, Mikayama et al. further teach that GIF is unable to carry out the function of MIF and MIF does not demonstrate GIF activity (see Abstract in particular).

Applicant is relying upon certain biological activities and the disclosure of a single species to support an entire genus. It is well known that minor structural differences among even structurally related compounds or compositions can result in substantially different biology, expression, and pharmacology of proteins. Therefore, structurally unrelated amino acids from 14 to about 20/30/40/50/60/70 amino acids in length having "SEQ ID NOS: 3-76 encompassed by the claimed invention other than "amino acids set forth by SEQ ID NO: 2" would be expected to have greater differences in their activities.

Since the amino acid sequence of a polypeptide determines its structure and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar functionality (e.g. generation of antibodies which recognize p33) requires a knowledge of, and guidance with regard to, which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification) and detailed knowledge of the ways in which a polypeptide's structure relates to it's functional usefulness. However, the problem of predicting polypeptide structure from mere sequence data of a single amino acid sequence and in turn utilizing predicted structural determinations to ascertain functional aspects the peptides and finally, what changes can be tolerated with respect thereto is complex and well outside the realm of routing experimentation.

In re Fisher, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Since the amino acid sequence of a polypeptide determined its structural and functional properties, predictability of which fragments will retain functionality requires knowledge of, and guidance with regard to, which amino acids in the polypeptide's sequence contribute to its structure, and therefore, function. The problem of predicting which fragments or

derivatives of a protein will retain functionality and which will not is complex and well outside the realm of routine experimentation. Because of the lack of sufficient guidance and predictability in determining which structures would lead to functional proteins or peptides with the desired properties and that the relationship between the sequence of a peptide and it's tertiary structure (i.e. its activity) was not well understood and was not predictable (e.g. see Ngo et al, in The Protein Folding Problem and Tertiary Structure Prediction, 1994. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495.); it would require an undue amount of experimentation for one of skill in the art to arrive at the breadth of proteins encompassed by the claimed invention.

With regard to the issue that the pending claims are not directed to antibody composition. Applicant's attention is respectively drawn to **claims 50-52.** Said claims specifically recited a kit comprising antibody or an antigen binding fragment. The Examiner failed to understand how said claims are not directed to antibody composition?

There is insufficient guidance and direction as to make and use SEQ ID NO: 2 (p33)-specific antibodies wherein the antibodies bind a peptide comprising from 14 to about 70 amino acids in length of SEQ ID NOS: 3-76, a peptide comprising residues 1-322 of SEQ ID NO: 2 for *in vivo* therapeutic purposes.

The genus encompasses antibodies that can specifically bind polypeptides wherein such polypeptides have numerous differences in amino acid sequences at positions other than the length of residues 1-322 of SEQ ID NO: 2 or peptides from 14 to about 70 amino acids in length of SEQ ID NOS: 3-76, including numerous differences in linear and conformational epitopes; and further encompasses antibodies which are coupled with an unlimited number of polypeptides as fusion proteins.

However, the present specification fails to provide sufficient disclosure of such polypeptides that maintain the structural and functional properties of the p33 polypeptide set forth in SEQ ID NO: 2 wherein the other amino acids can vary. The specification does not provide sufficient guidance as to which of the amino acids may be changed while p33 polypeptide/peptide structural or functional activity and specificity is retained. Further, the specification fails to provide guidance as to the unlimited number of polypeptides which can be fusion partners for peptides comprising from 14 to about 70 amino acids in length of SEQ ID NOS: 3-76 and residues 1-322 of SEQ ID NO: 2.

Coleman et al. (Research in Immunology, 1994; 145(1): 33-36) teach single amino acid changes in an antigen can effectively abolish antibody antigen binding. Abaza et al. (Journal of Protein Chemistry, Vol. 11, No. 5, 1992, pages 433-444) teach single amino acid substitutions outside the antigenic site on a protein effect antibody binding. Futher, Lederman et al. (Molecular Immunology 28: 1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). Additionally, Li et al. (PNAS 77: 3211-3214, 1980) disclose that dissociation of immunoreactivity from other biological activities when constructing analogs (see entire document).

Because of this lack of guidance, the extended experimentation that would be required to determine which modifications would be acceptable to retain occluding structural and functional activity, and the fact that the relationship between the sequence of a protein/peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g. see Ngo et al.; in The Protein Folding Problem and Tertiary Structure Prediction,1994, Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495.), it would require an undue amount of experimentation for one of skill in the art to arrive at the other polypeptides encompassed by the claimed invention.

The scope of the claimed p33-specific antibodies is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claimed invention. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's or peptide's amino acid sequence, and, in turn, nucleic acid sequence, and still retain similar biological activity or structural specificity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, the problem of predicting protein structure from mere sequence data of a limited number of proteins/nucleic acids and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect thereto is extremely complex and well outside the realm of routine experimentation.

Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use of the claimed p33-specific antibodies in manner reasonably correlated with the scope of the claims broadly including a broad number of structural changes encompassed by the genus of polypeptides as recited in the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 19 24 (CCPA 1970). Without such guidance, the changes which can be made in the amino acids and still maintain biological activity or structural specificity of p33 is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Applicant discloses on page 3, paragraph 2 that p33/p36 are activated in cancer cells following treatment with anti-cancer agents and that detection of protein activity with the antibody is a good therapeutic efficacy marker. Applicant further discloses on page 63, lines 17-18, and page 64, lines 10-12 that p33 activity is profound in cells undergoing apoptosis (i.e. cell death) and that elevated activity correlated with the induction of apoptosis. Finally, applicant discloses on page 6, paragraph 1, that preferred antibodies of the invention may be non-cross reactive with other polypeptides, including human polypeptides, or they may bind to non-human p33 or p63 polypeptides, but not to human p33 or p63; and page 5, lines 1-14 that said antibodies can alter, reduce, or inhibit the activity of p63 or p33.

Goyns et al. (Clin Oncol (R Coll Radiol) 1991 May;3(3):168-76) teach that cell proliferation is uncontrolled in cancer due to oncogenes. If, as applicant discloses, that p33 activity is increased following treatment with anti-cancer agents and that detection of protein activity with the antibody is a good therapeutic efficacy marker, the cancer cells expressing the increased p33 activity are dying. Therefore, it would not be beneficial to the patent suffering from cancer to use an antibody which binds p33 or a peptide of p33 to act as an antagonist of p33, because they could interfere with the cellular processes of apoptosis, and instead, enhance the uncontrolled cellular proliferation of the cancer cells, which is in direct contrast to the desired therapy. Indeed, enhancement of cancer cell growth is NOT a recognized therapy in the art.

Applicant has taught how to make and use SEQ ID NOS: 2-76 and residues 1-322 of SEQ ID NO: 2 to generate antibodies which bind to native p33 to serve as diagnostic markers of therapeutic efficacy of cancer treatments.

Applicant has not taught how to use any peptide of p33 or any antibody which binds to p33 as a therapeutic treatment regimen for patients suffering from cancer.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

8. Claims 1-8, 32- 37, 42-52 , 64, 65 and 67-75 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record set forth in the Office Action, filed on 09/30/02.

Applicant's arguments, filed 11/03/03 have been fully considered, but have not been found convincing.

Applicant asserts that Specification on pages 5 to 17 provides "an exhaustive and detailed teaching" that describes how to make and use various polypeptides or peptides and that Specification clearly indicates that "one aspect of the invention involves composition that comprises at least a first isolated peptide of from 9 to about 80 amino acids in length or at least first nucleic acid segment that encodes such a peptide,wherein the peptide comprises, consists essentially of a first contiguous animo acid sequence according to any one of SEQ ID NOs 3 –76."

In the Office Action, filed on 09/30/02. it was stated:

"Conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The sequences themselves are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993). A description of a genus of polypeptide/peptide sequences may be achieved by means of a recitation of a representative number of polypeptides/peptides having SEQ ID NOS: 3-76, residues 1-322 of SEQ ID NO: 2, or at least a first peptide and at least a second peptide of SEQ ID NOS: 3-76, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly&Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)".

Applicant is in possession of a polypeptide comprising SEQ ID NO: 2, a peptide consisting of residues 1-322 of SEQ ID NO: 2, and peptides consisting of SEQ ID NOS: 3-76, said SEQ ID NO: 2/peptides in a pharmaceutically acceptable excipient to be used to generate antibodies which recognize non-human p33 to diagnose the therapeutic effectiveness of cancer treatments; and wherein the immune complexes (said peptides/polypeptide--antibody) can be detected indirectly with another labeled antibody; a kit comprising said peptides.

Applicant is not in possession of any peptide/polypeptide comprising residues 1-322 of SEQ ID NO: 2, any peptide/polypeptide from 14 to about 20/30/40/50/60/70 amino acids in length comprising the amino acid sequence according to any one of SEQ ID NOS: 3-76, any other labeled peptide/polypeptide thereof for detection, diagnostic, or therapeutic purposes, any nucleic acid encoding said peptides/polypeptide, or any antibody to said peptide/polypeptide in a pharmaceutically acceptable excipient to be used for in vivo therapy of any disease, or for diagnosis of the therapeutic effectiveness of any disease other than cancer.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was

not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Guidelines for the Examination of Patent Applications Under the 35 U.S.C.112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No.4, pages 1099-1111, Friday January 5, 2001.

10. The following new ground of rejection is necessitated by amendment filed 11/03/03

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 2 , 8, 65 and 67-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection**.

"An isolated peptide consisting essentially of the amino acid sequence of any one of SEQ ID NOs...." claimed in Claims 2,8, and 65 ; and " An isolated peptide of from 14 to approximately 70/60/ /50/45/40/35/30/25/ amino acid in length, claimed in claims 67-75 represent(s) a departure from the specification and the claims as originally filed and applicant has not pointed out where the support come(s) from. The specification and the claims as originally field only support "An isolated peptide comprising of the amino acid sequence of any one of SEQ ID NOs...."

13. Claims 9, 12, 61-63, and 66 are allowable.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
January 26, 2004

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
1/26/04